510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K131900

1. Date of Submission: Jun 21, 2013

2. Sponsor Identification

Contec Medical System Co., Ltd
No. 24, Huanghe West Road, Economic & Technical Development Zone, Qinhuangdao, Hebei, 066004, China

Establishment Registration Number: 3006979678

Contact Person: Mr. Xueyong Li
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3. Submission Correspondent

Ms. Diana Hong& Mr. Tarzan Wang
Mid-Link Consulting Co., Ltd
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4. Proposed Device Identification

Proposed Device Name: CONTEC™ Electrocardiograph
Proposed Device Common Name: Digital Electrocardiograph

Regulatory Information:
Classification Name: Electrocardiograph
Classification: II;
Product Code: DPS
Regulation Number: CFR 870.2340
Review Panel: Cardiovascular

Intended Use Statement:

CONTEC™ Electrocardiographs, ECG100G/ECG300G/ECG1200G, are intended to acquire ECG signals from adult patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiographs shall be used in healthcare facilities by doctors and/or trained healthcare professionals.

5. Predicate Device Identification

510(k) Number: K113485
Predicate Device: Electrocardiographs
Product Model: ECG-1101G(I), ECG-1103G(I) and ECG-1112
Manufacturer: Shenzhen Carewell Electronics Co., Ltd

510(k) Number: K122712
Predicate Device: Digital Electrocardiographs
Product Model: iE 3S and iE 12
Manufacturer: Shenzhen Biocare Electronics Co., Ltd

6. Device Description

The proposed device, CONTEC™ Electrocardiograph, has three models: ECG100G, ECG300G and ECG1200G.

The three models all have three design modules, which are power module, signal acquisition and processing module and control module.

The proposed devices acquire ECG signal via twelve leads simultaneously, display or print waveform of

ECG signal via single channel/ three channel/ twelve channel.

The proposed device, model ECG100G, has two recording modes, including automatic mode and manual mode; the other two models, ECG300G and ECG1200G have three recording modes, including automatic mode, manual mode and rhythm mode.

The proposed devices are designed to acquire, process, display and record ECG signals from patient body surface by ECG electrodes. After been amplified and filtered, the ECG signal waveforms are displayed on the LCD screen and recorded on the paper through thermal printer. ECG data, waveform and patient information could be stored in the memory of the device;

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

IEC 60601-1:1988+ A1:1991+ A2:1995, Medical electrical equipment, Part 1: General requirements for safety.

IEC 60601-1-2: 2007, Medical electrical equipment, Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests

IEC 60601-2-25:1993+A1:1999, Medical electrical equipment, Part 2-25: Particular requirements for the safety of electrocardiographs.

ANSI/AAMI EC11:1991/(R) 2007, Diagnostic electrocardiographic devices

8. Substantially Equivalent (SE) Conclusion

The following table compares the DEVICE to the predicate devices with respect to intended use, technological characteristics and product function, etc.

Table 3-1 Comparison of Technology Characteristics

ITEM	Proposed Device CONTEC™ Electrocardiograph	Predicate Device K113485	Predicate Device K122712
Model	ECG100G/ECG300G/ECG1200G	ECG-1101G(I)/ECG-1103G(I)/ ECG-1112	iE 3S/ iE 12
Code	DPS	SAME	SAME
Regulation No.	CFR 870.2340	SAME	SAME
Channel	1/3/12 channel	SAME	SAME
Acquisition mode	Simultaneous 12-lead acquisition	SAME	SAME
Recording mode	ECG100G:Automatic / Manual ECG300G/ECG1200G: Automatic / Manual/rhythm	Automatic / Manual/rhythm	Automatic / Manual/rhythm
Patient leak current	<10μA	SAME	SAME
Frequency response	0.05~150Hz	SAME	SAME
Noise level	<15μVp-p	SAME	SAME
CMRR	>60 dB >100 dB (with AC filter)	SIMILAR	SIMILAR
Measurement/ Analysis Function	No	Yes	No
Input CIR current	≤50nA	SAME	SAME
Input impedance	>50MΩ	SAME	SAME

The proposed device, CONTEC™ Electrocardiograph, is determined to be Substantially Equivalent (SE) to the predicate devices, Electrocardiographs (K113485) and Digital Electrocardiographs (K122712), in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

March 5, 2014

Contec Medical System Co., Ltd.
c/o Ms. Diana Hong
Regulatory Consultant
P.o. Box 120-119
Shanghai, 200120 CHINA

Re: K131900
Trade/Device Name: Contec electrocardiograph
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: January 16, 2014
Received: January 24, 2014

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

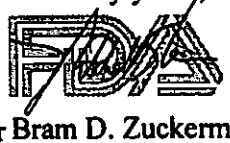
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): __K131900_____

Device Name: __ CONTEC Electrocardiograph____

Indications For Use: CONTEC Electrocardiographs, ECG100G/ECG300G/ECG1200G, are intended to acquire ECG signals from adult patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiographs shall be used in healthcare facilities by doctors and/or trained healthcare professionals.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Date: 2014.03.05 09:31:51 -05'00'

for Bram Zuckerman

Prescription Use __X__ OR **Over-The-Counter Use** _____
(Per 21 CFR 801.109)